

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluation of Managing Cancer and Living Meaningfully (CALM) in people with advanced non-small cell lung cancer treated with immunotherapies or targeted therapies: protocol for a single-arm, mixed-methods pilot study
AUTHORS	Lynch, Fiona; Rodin, Gary; Jefford, Michael; Duffy, Mary; Lai-Kwon, Julia; Heynemann, Sarah; Mileshekin, Linda; Briggs, Lisa; Burke, John; Leigh, Lilian; Spelman, Tim; Ftanou, Maria

VERSION 1 – REVIEW

REVIEWER	Lisa Mackenzie The University of Newcastle, Priority Research Centre for Health Behaviour
REVIEW RETURNED	12-Apr-2023

GENERAL COMMENTS	<p>Thank you for the opportunity to review this research protocol paper. The paper is well written and the proposed study is methodologically sound. My only suggested revision would be to include some more detail on the exclusion criteria "currently receiving formal psychological therapy". Will this be assessed via self-report? Could a patient choose to pause their psychological therapy in order to become eligible for this study? Does the formal psychological therapy need to be for cancer related concerns, or would potential participants be excluded if they happened to be accessing support for pre-existing issues (e.g. relating to work or relationship concerns).</p> <p>I look forward to reading the findings of this study once completed.</p>
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REVIEWER	Huaidong Cheng Anhui Medical University
REVIEW RETURNED	03-Jun-2023

GENERAL COMMENTS	<p>CALM is a brief evidence-based intervention for patients with advanced cancer that has potential to address psychological concerns. This protocol was designed to evaluate the effect of Managing Cancer and Living Meaningfully (CALM) in people with advanced NSCLC treated with novel therapies. The content is comprehensive and reasonable. A more detailed description of the definition of novel therapies will provide greater clarity on the enrolled patients.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. Lisa Mackenzie, The University of Newcastle

Comments to the Author:

Thank you for the opportunity to review this research protocol paper. The paper is well written and the proposed study is methodologically sound. My only suggested revision would be to include some more detail on the exclusion criteria "currently receiving formal psychological therapy". Will this be assessed via self-report? Could a patient choose to pause their psychological therapy in order to become eligible for this study? Does the formal psychological therapy need to be for cancer related concerns, or would potential participants be excluded if they happened to be accessing support for pre-existing issues (e.g. relating to work or relationship concerns).

I look forward to reading the findings of this study once completed.

Thank you for your feedback. We have updated the exclusion criteria to state: "currently receiving any ongoing formal psychological therapy according to self-report for their cancer or other concerns at the time of consent."

We have also added: "If a patient initiated wanting to pause their current therapy to participate in the CALM project for the duration of their CALM participation, this may no longer be an exclusion criteria if deemed clinically appropriate by the research staff member."

We appreciate the interesting point you raise regarding what type of pre-existing support they may have been receiving, and we have now added this to our limitations:

A further limitation of the study design is the exclusion of people currently receiving formal psychotherapy. This may limit access to cancer-specific psychological support to potential participants who may be already receiving non-cancer related psychological support. This exclusion criterion is needed due to the potential overlap of CALM content domains with other psychological therapies such the focus on relationships, identity, and sense of meaning. However, future work could consider offering participants the opportunity to pause their current therapy if they would like to participate in the CALM study.

Reviewer: 2

Dr. Huaidong Cheng, Anhui Medical University

Comments to the Author:

CALM is a brief evidence-based intervention for patients with advanced cancer that has potential to address psychological concerns. This protocol was designed to evaluate the effect of Managing Cancer and Living Meaningfully (CALM) in people with advanced NSCLC treated with novel therapies. The content is comprehensive and reasonable. A more detailed description of the definition of novel therapies will provide greater clarity on the enrolled patients.

Thank you for this encouraging feedback. We have reviewed the manuscript and in sentence two of the background we had already defined novel therapies as immunotherapies or targeted therapies: "introduction of immunotherapies (IT) and targeted therapies (TT), (subsequently referred to as 'novel therapies')".

We have amended the document to ensure that prior to this we have replaced 'novel therapies' with "immunotherapies or targeted therapies" to provide clarity and have amended our title to 'immunotherapies or targeted therapies'. We hope this provides the clarity needed.